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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,548	07/30/2003	Ralph A. Backhaus	7467	7467

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EXAMINER

LANKFORD JR, LEON B

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 02/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/630,548	Applicant(s) BACKHAUS, RALPH A.	
	Examiner Leon Lankford	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/23/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 8-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments filed 11/23/05 have been fully considered but they are not persuasive to overcome all the rejections of record. The Double Patenting, 101 and 112 rejections have been overcome by applicant's amendment.

Applicant argues that there is no reasonable expectation of success that a known antioxidant will treat (or reduce the risk of) ischemic injury and that some antioxidants have been shown to be ineffective. Applicant's arguments have been considered however a showing to overcome a prima facie case of obviousness must be clear and convincing(In re Lohr et al. 137 USPQ 548) as well as commensurate in scope with the claimed subject matter (In re Lindner 173 USPQ 356; In re Hyson, 172 USPQ 399 and In re Boesch et al., 205 USPQ 215 (CCPA 1980). It should be noted that applicant's claims do not require a specific level of treatment or reduction of risk and thus with the suggestion of Backhaus, there is a reasonable expectation of success of at least some positive effect on reducing the risk of or treating ischemic injury by administering the known antioxidant enzyme.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-6 remain rejected under 35 U.S.C. 102(b) as being anticipated by Backhaus et al (6132711).

Backhaus disclose pharmaceutical compositions of allene oxide synthase in a pharmaceutical carrier. The reference clearly anticipates the claim 7 subject matter.

Claims 4-6 require a preventing effect by the administration of the enzyme. As Backhaus teaches an administration of the enzyme to an individual, the same prophylaxis effects claimed must have been accomplished in the earlier method of Backhaus. As the target (an individual) and the steps (administration of the enzyme) are identical in the instant claims and in the patent, any result of the instant claims must have been inherently accomplished by the patent's method. The reference anticipates the claim subject matter.

Applicant's amendment is not sufficient to overcome the rejection of claims 4-6. All individuals in Backhaus are in risk of the claimed injuries and thus the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 & 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Backhaus et al (6132711).

Backhaus disclose pharmaceutical compositions of allene oxide synthase in a pharmaceutical carrier. It would have been obvious at the time the invention was made to treat ischemic injuries and reduce the risk thereof, myocardial or cerebrovascular, because the reference clearly suggests the use of the enzyme preparation to treat ischemic disorders as the enzyme works well as an enzymatic antioxidant acting particularly on lipid peroxides:

Antioxidants, such as beta-carotene, SOD, allopurinol, and catalase, have been used in treating ischemia following surgery or injury in biological organisms. (Konovalova et al., Arkh. Patol. 51(6): 19-24 (1989) (Abstract); Minor et al., Surg. Today 23(8): 728-732 (1993) (Abstract); Maksimenko et al., Eksp. Kin. Farmakol. 56(5): 14-18 (1993) (Abstract); Kloner, Circ. Res. 64(1): 86-96 (1989) (Abstract); Nayak et al., Invest. Ophthalmol. Vis. Sci. 34(6): 2018-2022 (1993) (Abstract); Baker et al., Ann. Surg. 202(5): 628-641 (1985) (Abstract); Gross et al., Am. J. Physiol. 250(3Pt.2): H372-H377 (1986) (Abstract); Zweier et al., J. Clin. Invest. 80(6): 1728-1734 (1987) (Abstract); Singh et al., Mol. Cell. Biochem. 125(2): 97-104(1993); Nelson et al., Free Radic. Biol. Med. 16(2): 195-200 (1994) (Abstract); Burton, Am. J. Physiol. 248(5 Pt. 2): H637-H643 (1985) (Abstract); Chi et al. Circ. Res. 64(4): 665-675 (1989) (Abstract); Miura et al. Jpn. Circ. J. 53(7): 786-794 (1989) (Abstract); Konovalova et al. Biull Eksp Biol. Med. 98(8): 153-156 (1984) (Abstract); Gutkin et al. Biull. Eks. Biol. Med. 93(1): 33-35 (1982) (Abstract); and Wang et al., Hua. Hsi. I. Ko. Ta. Hsueh. Pao. 25(1): 62-65 (1994) (Abstract)). Ischemia is a deficiency of blood in a biological organism due to functional constriction or actual obstruction of a blood vessel, common in surgery, that causes cell tissue damage as a result of oxidation. Myocardial ischemia is a deficiency of blood supply to the heart muscle.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made especially in the absence of evidence

to the contrary.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

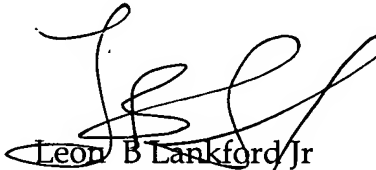
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Lankford whose telephone number is 571-272-0917. The examiner can normally be reached on Mon-Thu 7:30-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leon B Lankford Jr
Primary Examiner
Art Unit 1651